

REMARKS/ARGUMENTS

The present amendment is submitted with a Request for Continued Examination. Applicants' previous response, filed October 6, 2010, was not entered because the claim amendments allegedly raised new issues. New claims 72-77 are based on the claims presented in the October 6 response. New claims 72 and 73 find support in cancelled claims 17 and 18 and in the specification at page 3, lines 11-13. The generic term for TWEEN 80®, polysorbate 80, has been used in the claims and is supported, for example, at page 3, line 10. Claims 74-76 correspond to cancelled claims 29, 31, and 32, respectively. New claim 77 finds support at page 3, line 13.

Applicants would like to acknowledge the courtesies extended by the Examiner in the telephone interview on December 20, 2010. During the interview, the non-obviousness of un-entered claims 73 and 74, directed to particular embodiments of the invention, was discussed. The currently presented claims correspond to un-entered claims 73 and 74. Applicants understand from the Advisory Action mailed October 19, 2010 that the pending claims overcome the rejections under 35 U.S.C. § 112, first and second paragraphs. Thus, only the rejection under 35 U.S.C. §103(a) is addressed below.

In the Office Action, claims 13-18, 28-32 and 69-71 were rejected for allegedly being obvious over US Patent No. 5,618,786 and US Patent No. 6,267,958 in view of US Patent No. 6,653,284 and US Patent No. 5,166,134. This rejection is respectfully traversed to the extent it is applied to the present claims.

As discussed during the interview, the specification provides evidence that the claimed compositions are particularly effective in maintaining stability of AAT a variety of temperatures. It is well settled that the Examiner must also consider evidence of surprising or unexpected results of the claimed invention. MPEP §2145.

As explained in the paragraph bridging pages 13 and 14 of the specification, a number of AAT formulations were tested for stability for up to 6 months at -70°C, 5°C, 25°C, 40°C, 50°C, and 60°C (see Table 2, pages 20-21). As shown in Table 1 on page 19, the excipients tested were trehalose (0% to 5%), Tween-80 (0.0 % to 0.5%), and methionine (5mM).

The formulations were evaluated by conducting assays for functional activity, total protein and aggregation (i.e., % monomer).

As explained on pages 18-19, the nine formulations tested all showed significant improvements in stability relative to AAT compositions without stabilizers. Inclusion of trehalose at 2.5% (Formulas 5-8 in Table 1) had the most appreciable beneficial effect on stability of the various factors tested (*see* Table 3, pages 22-23). On page 19, lines 10-11, the inventors conclude that a formulation as currently claimed is a particularly effective formulation.

The results presented here establish the surprising effectiveness of the claimed compositions to maintain stability of AAT for up to 6 months, at a variety of temperatures. None of the cited references disclosed or suggest the surprising effectiveness of the claimed compositions, as presently claimed. In view of the surprising properties of the present invention, withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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